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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,681	02/25/2004	Shanta Modak	A34446-A-PCT-USA-AA	3011
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BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 12/23/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary	Application No. 10/786,681	Applicant(s) MODAK ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 10/02/2008. Upon entering the amendment, the claims 1-2 are pending and presented for examination.

Response to Arguments

2. Applicant's arguments filed on 10/02/2008 with respect to claims have been fully considered but they are not persuasive. The 103(a) rejection of Jampani et al (US 6,022,551) and Modak et al (US 5,965,610) in view of Beilfuss et al (US 5,516,510) is maintained and made **FINAL**.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jampani et al (US 6,022,551) and Modak et al (US 5,965,610) in view of Beilfuss et al (US 5,516,510).

Jampani et al discloses a composition comprising antimicrobial agents such as bis-guanides, chlorhexidine digluconate, parachlorometaxyleneol, quaternary ammonium compounds, their combinations and the like. And also discloses that the benzalkonium chloride is used from about 0.02% to about 1.0% and chlorhexidine digluconate ranges from about 0.1% to about 4 %.(see col2. lines 40-49). And also discloses that the antimicrobial compositions are effective in controlling microorganisms when an effective amount of the composition is topically applied to a substrate or location, such as the hands, acne sites or injection site for catheters etc. And further the compositions were evaluated using an in-vivo bactericidal test against eight representative microorganisms (gram negative and gram positive).

Modak discloses a composition comprising an irritant-inactivating agent such as anti-microbial agent and an anti-binding substance, which substantially prevents the irritant-inactivating agent from binding to the surface (e.g. soluble zinc compounds). And also discloses various anti-microbial agents such as iodine, benzalkonium chloride, phenoxyethanol, triclosan, chlorhexidine digluconate (see column 5, lines 2-25). Further discloses pharmaceutically acceptable cationic substance used to block binding sites on the skin such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate, and zinc salicylate (see column 7, lines 10-12) and when the irritant-inactivating agent is an anti-microbial agent, and when the anti-binding substance is zinc, the ratio of the amount of

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the anti-microbial agent to the amount of the anti-binding substance is preferably from about 1:13 to about 2:1 (see column 9, lines 2-6). Further cationic substance include quaternary ammonium compounds such as amino acids and peptides, quaternized proteins such as cocodimonium hydroxypropyl hydrolyzed keratin (see column 7, lines 14-23).

Jamapani and Modak meet the claims limitation as stated above, but fail to include octoxyglycerin in the composition.

Beilfuss discloses a composition comprising anti-microbial agents and glycerin monoalkyl ethers such as octoxyglycerin. The preferred anti-microbial agents include phenoxy ethanol, chlorhexidine salts, as well as salts of other cation-active compounds with deodorizing action (col. 3 lines 15-37). The glycerin monoalkyl ethers incorporated are mild and skin-compatible, have a good spreading capacity and confer a pleasant skin feeling, they are particularly suitable for deo-compositions. The glycerin monoalkyl ether, particularly 2-ethylhexyl glycerin ether (used in concentration in the range 0.01% to 20%) displays good antimicrobial effect, inhibits enzymes or catalysts which are responsible for the odor formation from the primarily odorless sweat, have an effect on the sweat-gland secretion, whereby sweat secretion is reduced. And further formulations were tested in the agar hole test for effectiveness against deo-germs i.e., gram (+) and gram (-) microorganisms (see col. 4 table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use combination of antimicrobial agents that have potential application in topical skin care products, like gels, creams, lotions, scrubs, pre-operative

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preparations, therapeutics and other applications against disease causing pathogens, as taught by Jampani and Modak, combine it with antimicrobial composition comprising octoxyglycerin that enhances the activity of antimicrobial agents and have good penetration capacity into the skin, as taught by Beilfuss, and produce the instant invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 10/02/2008 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention encompasses, the unexpected discovery that octoxyglycerin, when combined with a benzalkonium chloride and a second antimicrobial agent e.g., bisguanide, exhibits a synergistic increase in the combined antimicrobial efficacy of the three antimicrobial agents.

This argument is unpersuasive because synergism of the compounds is taught in prior art i.e., glycerin monoalkyl ethers (Sensiva) with other antimicrobial agents shows an increase in synergistic effects (see col. 3 lines 39-41). Further, Modak teaches the synergistic activity of BZK with PCMX (parachlorometaxylenol, an antimicrobial agent) and CHX (chlorhexidine, see col. 6 lines 10-15). Therefore the combination of Sensiva with BZK and CHG would have resulted synergistic effect and would promote the

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antimicrobial effects of a diverse array of compounds, including quaternary ammonium compounds, biguanides, chlorinated phenols, metal salts, antifungal azoles etc.

Applicant's are advice to show, how the instant claims is superior, combined to the prior art.

The skilled artisan would reasonably expected success in combining the prior art reference i.e., combining Sensiva with BZK and CHG and other antimicrobial agents, since the mechanism of synergistic action of Sensiva would enhance the antimicrobial effects particularly against gram(+) bacteria which are particularly relevant from the point of view of causing odor. "[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR international Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1390.

Applicant also argues that none of the formulations for which Beilfuss discloses quantifiable antimicrobial effects comprise octoxyglycerin, a quaternary ammonium compound and second antimicrobial agents.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642, 642 F.2d 413, 208 USPQ 871 (CCPA 1981; *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Beilfuss reference is combined for its teaching of knowledge in the art of using Sensiva in combination with other antimicrobial agents to promote the antimicrobial effects of a diverse array of compounds.

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The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case obviousness is presented.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 B2 (herein after '846). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-2 are drawn to an

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antimicrobial composition comprising octoxyglycerin, a quaternary ammonium compound, an antimicrobial agent selected from the group consisting of a biguanide compound, triclosan, phenoxyethanol, an iodine compound and parachlorometaxylenol and zinc compounds effective in inhibiting gram(+) and gram(-) bacteria, and '846 are drawn an antimicrobial composition comprising synergistic effective amounts of octoxyglycerin, a quaternary ammonium compound, and an antimicrobial agent selected from the group consisting of biguanide compound, tirclosan, phenoxyethanol, an iodine compound and parachlorometaxylenol. And both the composition are tested for antimicrobial activity against gram (+) and gram (-) bacteria. The difference is that claims of '846 disclose ingredients having a synergistic combination of octoxyglycerin and at least one other antimicrobial agent compositions without causing increased irritation to the skin of the average user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use different numbers and combinations of antimicrobial agents during the process of routine optimization, in order to enhance the antimicrobial effectiveness of the composition

Applicant asserts that the examiner to hold the present rejection in abeyance. This is not found persuasive because the provisional type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5]. This rejection is maintained and is not held in abeyance.

Conclusion

1. No claims are allowed at this time.
2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr